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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/325,603	06/03/99	SVENDSEN	A	4394.214-US

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EXAMINER	
SLOBODYANSKY,E	
ART UNIT	**PAPER NUMBER**
1652	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 09/325,603	Applicant(s) Svendsen et al.
	Examiner Elizabeth Slobodyansky	Group Art Unit 1652

☒ Responsive to communication(s) filed on *Jul 17, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *71 and 76-78* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *71 and 76-78* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413 (Paper #10 ½)

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

The request filed on July 17, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/325,603 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed July 17, 2000 canceling claims 72-75, amending claim 71 and adding claims 76-78 has been entered.

Claims 71 and 76-78 are pending.

Claim Objections

Claim 78 is objected to because of the following informalities: on line (ii) "part of" typed twice. Appropriate correction is required.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 76-78 are drawn to a method of use of a three-dimensional alpha-amylase structure. A genus of a a three-dimensional alpha-amylase structure is a vast genus encompassing structures of all amylases.

The specification teaches the X-ray crystallographic three-dimensional structure of one amylase, α-amylase having amino acid sequence of SEQ ID NO: 13, based on the coordinates depicted in Appendix. This is the first three-dimensional structure of a bacterial alpha- amylase. It exhibits A, B and C domains and three metal ions at the junction of the A and B domains. It is known in the art that the three-dimensional structure of the same enzyme based on a different crystal may have different coordinates. It means that the amylase of SEQ ID NO:13 can have the structure with coordinates different from the depicted in Appendix if obtained from a different crystal. Further, the art of crystallization is unpredictable. The specification does not contain any disclosure of coordinates for other amylases. This is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus of three-dimensional structure of α-amylase exhibiting the requisite properties.

One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Thus, a method of use of a three-dimensional alpha-amylase structure lacks sufficient written description needed to practice the invention of claims 76-78.

Claims 76-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method using a three-dimensional structure having coordinates depicted in Appendix, does not reasonably provide enablement for a method of use of any three-dimensional alpha-amylase structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Factors pertinent to this discussion include predictability of the art, guidance in the specification, breadth of claims, and the amount of experimentation that would be necessary to use the invention.

In order to practice methods of claims 76-78 one skilled in the art would need an X-ray crystallographic three-dimensional structure of an unspecified α-amylase. Although the specification teaches the X-ray crystallographic three-dimensional structure of α-amylase having amino acid sequence of SEQ ID NO: 13 based on the coordinates depicted in Appendix, it does not teach an X-ray crystallographic three-dimensional structure of any other α-amylase. The field of the enzyme X-ray crystallography requires highly specialized skills, and is highly unpredictable. The state of the art disclose an X-ray crystallographic three-dimensional structure of no bacterial α-amylase prior to the instant invention. In the prior art only the tree-dimensional structures of α-amylases from *Aspergillus oryzae*(SEQ ID NO:10 in the instant specification), barley and pig pancreas are known. In general, "**[c]rystallization** is usually quite difficult to achieve, and crystal growth can be slow; in some cases it may require months for sufficiently large crystals (0.5 mm) to grow from microcrystals. The formation of crystals is also critically dependent on a number of different parameters, including pH, temperature, protein concentration, the nature of the solvent and precipitant as well as the presence of added ions or ligands to the protein." (In Branden et al., page 271, 1st paragraph, cited on form PTO-892 mailed March 17, 2000).

Therefore, one of ordinary skill would require the information regarding a three-dimensional structure of an α-amylase, in order to make steps required by methods of claims 76-78 and use methods of claims 76-78 in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71 and 76-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 71 and 76-78 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

In claim 71, it appears that step (a) includes two steps: 1) identifying a structural part in the structure depicted in Appendix 1 and 2) identifying "a corresponding structural part in said parent alpha-amylase". It is unclear how a corresponding part of a parent amylase was identified.

Claim 76 is confusing because of the following. It is unclear which alpha-amylase three-dimensional structure is recited in (a). If this is of a parent amylase, then in (b) it is unclear to what "the structural part" (first occurrence) in "the structural part or a corresponding structural part in said parent alpha-amylase" is referring to. The step of obtaining a three-dimensional structure is omitted.

Claims 77 and 78 are confusing because of the following. It is unclear which alpha-amylase three-dimensional structure is recited in (a). If this is of a parent amylase, then it is unclear to what "the structural part" in "the structural part or [in] a corresponding structural part in said parent alpha-amylase" is referring to. Further, it appears that the step connecting (a) and (b) is omitted.

Claims 77 and 78 recites the limitation "tree-dimensional alpha-amylase structure" in (a). There is insufficient antecedent basis for this limitation in the claim.

Claim 77 is confusing because it refers to "residues 104-205 in the structure depicted in Appendix 1". Residues 104-205 are located in SEQ ID NO:2 (page 8, line 2) whereas residues 104-205 of the structure depicted in Appendix 1 are residues of SEQ ID NO:13/ SEQ ID NO:4.

Claim 78 is confusing because it refers to the list of residues "of the structure depicted in Appendix 1". The specification teaches that these residues are located in SEQ ID NO:2 whereas the structure depicted in Appendix 1 is that of SEQ ID NO:13.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 71 and 76-78 are rejected under the judicially created doctrine of double patenting over claims 1-14 of U. S. Patent No. 5,989,169 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method of use of a three-dimensional structure of α-amylase having amino acid sequence of SEQ ID NO: 13 based on the coordinates depicted in Appendix for modelling of a structure of a parent amylase in order to identify residues/regions responsible for a specific requisite property.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution

of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

This is a continuation (CPA) of applicant's earlier Application No. 09/325,603. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

August 24, 2000